EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to beta-galactosidase from Streptococcus thermophilus and reduction of gastrointestinal discomfort pursuant to Article 14 of Regulation (EC) No 1924/2006

EFSA Publication

Link to article, DOI:
10.2903/j.efsa.2014.3841

Publication date:
2014

Document Version
Publisher's PDF, also known as Version of record

European Food Safety Authority

EFSA Journal 2014;12(10):3841

SCIENTIFIC OPINION

Scientific Opinion on the substantiation of a health claim related to beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort pursuant to Article 14 of Regulation (EC) No 1924/2006[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort. According to the applicant, the food constituent which is the subject of the claim is beta-galactosidase from *Streptococcus thermophilus*. *Streptococcus thermophilus* is added to infant formulae in the production process for fermentation purposes and the live organisms are inactivated after the fermentation process. The Panel considers that the food constituent, beta-galactosidase from *Streptococcus thermophilus*, under the conditions of use proposed by the applicant, is sufficiently characterised. The claimed effect proposed by the applicant is "reduction of gastro-intestinal discomfort". The target population proposed by the applicant is infants and young children. The Panel considers that reduction of gastrointestinal discomfort is a beneficial physiological effect. No human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant. The Panel concludes that a cause and effect relationship has not been established between the consumption of beta-galactosidase which is produced by *Streptococcus thermophilus* (subsequently inactivated) during fermentation of an infant formula and reduction of gastrointestinal discomfort.

KEY WORDS

beta-galactosidase, lactase, *Streptococcus thermophilus*, gastrointestinal discomfort, infants, children

[1] On request from the Competent Authority of France following an application by Specialised Nutrition Europe (SNE), Question No EFSA-Q-2008-148, adopted on 18 September 2014.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Claims: Carlo Agostoni, Jean-Louis Bresson, Susan Fairweather-Tait, Marina Heinonen, Ambroise Martin, Hildegard Przyrembel, Yolanda Sanz, Alfonso Siani, Anders Sjödin, Sean (J.J.) Strain, Inge Tetens, Hendrik Van Loveren, Hans Verhagen and Peter Willatts for the preparatory work on this scientific opinion.

Suggested citation: EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the substantiation of a health claim related to beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2014;12(10):3841, 8 pp. doi:10.2903/j.efsa.2014.3841

Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following an application from Specialised Nutrition Europe (formerly IDACE), submitted for authorisation of a health claim pursuant to Article 14 of Regulation (EC) No 1924/2006 via the Competent Authority of France, the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver an opinion on the scientific substantiation of a health claim related to beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort.

The scope of the application was proposed to fall under a health claim referring to children's development and health.

According to the applicant, the food constituent which is the subject of the claim is "microbial beta-galactosidase present as an endogenous component of some infant nutrition products". Following a request for clarification from EFSA during the validation period of the application, the applicant explained that the food constituent which is the subject of the claim is beta-galactosidase from *Streptococcus thermophilus*. *Streptococcus thermophilus* is added to infant formulae in the production process for fermentation purposes and the live organisms are inactivated after the fermentation process. The Panel considers that the food constituent, beta-galactosidase from *Streptococcus thermophilus*, under the conditions of use proposed by the applicant, is sufficiently characterised.

The claimed effect proposed by the applicant is "reduction of gastro-intestinal discomfort". The target population proposed by the applicant is infants and young children. The Panel considers that reduction of gastrointestinal discomfort is a beneficial physiological effect.

The Panel notes that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of beta-galactosidase which is produced by *Streptococcus thermophilus* (subsequently inactivated) during fermentation of an infant formula and reduction of gastrointestinal discomfort.

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BACKGROUND

Regulation (EC) No 1924/2006[4] harmonises the provisions that relate to nutrition and health claims, and establishes rules governing the Community authorisation of health claims made on foods. As a rule, health claims are prohibited unless they comply with the general and specific requirements of this Regulation, are authorised in accordance with this Regulation, and are included in the lists of authorised claims provided for in Articles 13 and 14 thereof. In particular, Articles 14 to 17 of this Regulation lay down provisions for the authorisation and subsequent inclusion of reduction of disease risk claims and claims referring to children's development and health in a Community list of permitted claims.

According to Article 15 of this Regulation, an application for authorisation shall be submitted by the applicant to the national competent authority of a Member State, which will make the application and any supplementary information supplied by the applicant available to the European Food Safety Authority (EFSA).

STEPS TAKEN BY EFSA

- The application was received on 14/02/2008.
- The scope of the application was proposed to fall under a health claim referring to children's development and health.
- On 26/03/2008 and on 29/11/2013, during the validation process of the application, EFSA sent a request to the applicant to provide missing information.
- On 12/08/2013 and on 21/01/2014, respectively, EFSA received the missing information as submitted by the applicant.
- The scientific evaluation procedure started on 23/01/2014.
- On 06/03/2014, the Working Group on Claims of the NDA Panel agreed on a list of questions for the applicant to provide additional information to accompany the application. The clock was stopped on 11/03/2014 and was restarted on 04/07/2014, in compliance with Article 16(1) of Regulation (EC) No 1924/2006>.
- On 04/07/2014, EFSA received the requested information (which was made available to EFSA in electronic format on 01/07/2014).
- During its meeting on 18/09/2014, the NDA Panel, having evaluated the data submitted, adopted an opinion on the scientific substantiation of a health claim related to beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort.

TERMS OF REFERENCE

EFSA is requested to evaluate the scientific data submitted by the applicant in accordance with Article 16 of Regulation (EC) No 1924/2006. On the basis of that evaluation, EFSA will issue an opinion on the scientific substantiation of a health claim related to: beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort.

EFSA DISCLAIMER

The present opinion does not constitute, and cannot be construed as, an authorisation for the marketing of "beta-galactosidase from *Streptococcus thermophilus*", a positive assessment of its safety, nor a

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

decision on whether "beta-galactosidase from *Streptococcus thermophilus*" is, or is not, classified as a foodstuff. It should be noted that such an assessment is not foreseen in the framework of Regulation (EC) No 1924/2006.

It should also be highlighted that the scope, the proposed wording of the claim, and the conditions of use as proposed by the applicant may be subject to changes, pending the outcome of the authorisation procedure foreseen in Article 17 of Regulation (EC) No 1924/2006.

INFORMATION PROVIDED BY THE APPLICANT

Applicant's name and address: Specialised Nutrition Europe (formerly IDACE), 9-31 Avenue des Nerviens, 1040 Brussels, Belgium.

Food/constituent as stated by the applicant

According to the applicant, the food constituent which is the subject of the claim is "microbial beta-galactosidase present as an endogenous component of some infant nutrition products". In response to a request by EFSA for clarification, the applicant explained that the food which is the subject of the claim is beta-galactosidase from *Streptococcus thermophilus*. *Streptococcus thermophilus* is added to formulae in the production process for fermentation purposes and is subsequently inactivated.

Health relationship as claimed by the applicant

According to the applicant, the claimed effect refers to the reduction of gastrointestinal discomfort.

Wording of the health claim as proposed by the applicant

The applicant has proposed the following wording for the health claim: "Lactase for comfortable digestion".

Specific conditions of use as proposed by the applicant

According to the applicant, the target population is infants and young children between birth and three years. In a response to a request by EFSA for clarification, the applicant indicated that the effect is expected to occur in infants and young children suffering from transient lactase deficiency owing to the damage of intestinal cells, caused by inflammation, allergic reactions or infections, resulting in a reduction of lactase activity.

The applicant has proposed an intake of beta-galactosidase of at least 135 U/day in lactase supplements, 18 U/100 mL in infant and follow-on formula.

ASSESSMENT

1. Characterisation of the food/constituent

According to the applicant, the food constituent which is the subject of the claim is "microbial beta-galactosidase present as an endogenous component of some infant nutrition products". Following a request for clarification from EFSA during the validation period of the application, the applicant explained that the food constituent which is the subject of the claim is beta-galactosidase from *Streptococcus thermophilus*. *Streptococcus thermophilus* is added to infant formulae in the production process for fermentation purposes and the live organisms are inactivated after the fermentation process.

For the scientific substantiation of the claim, the applicant provided one human intervention study which investigated the effect of an infant formula fermented with *Streptococcus thermophilus* and *Bifidobacterium breve* and thickened with maize and potato starch compared with an unfermented infant formula with no added starch.

During the stop-the-clock procedure, EFSA informed the applicant that, in the context of the information provided, EFSA would consider the food which is the subject of the claim to be the specific infant formula produced with *Streptococcus thermophilus* producing beta-galactosidase and asked the applicant to provide further details to allow the characterisation of the formula. In particular, the applicant was asked to consider that during the fermentation process, and the process of inactivation of the bacterium, constituents other than beta-galactosidase are produced and also that no studies had been provided which allowed an assessment of an independent effect of beta-galactosidase from *Streptococcus thermophilus.*

In reply, the applicant maintained that the food constituent which is the subject of the claim is beta-galactosidase from *Streptococcus thermophilus* and informed EFSA that the applicant "did not consider it relevant to characterise the amount of Streptococcus added before fermentation, nor the fermentation process, as the resulting amount of beta-galactosidase in the end product was the claimed constituent".

The Panel notes that beta-galactosidase, which is produced by *Streptococcus thermophilus* (subsequently inactivated) during fermentation of an infant formula, is a well-characterised enzyme and its activity can be measured in foods by established methods.

The Panel considers that beta-galactosidase from *Streptococcus thermophilus*, under the conditions of use proposed by the applicant, is sufficiently characterised.

2. Relevance of the claimed effect to human health

The claimed effect is "reduction of gastro-intestinal discomfort". The target population proposed by the applicant is infants and young children.

Unexplained bouts of crying in young infants, traditionally, have been attributed to gastrointestinal disturbances and pain (Shamir et al., 2013). A specific term, infant colic, is commonly used to reflect this situation in young infants. However, there is no proof that crying in infant colic is caused by pain in the abdomen or any other body part. Infant colic has been included in the list of childhood functional gastrointestinal disorders of the Rome III Coordinating Committee with diagnostic criteria based on infant crying time (Hyman et al., 2006). Infant pain and discomfort behaviours can also be measured objectively using validated pain scales and infant distress behaviour can be assessed by trained observers using behaviour logs or rating scales, supported by evidence for their validity (Shamir et al., 2013). The Rome III criteria and validated tools can be used to assess gastrointestinal discomfort in infants once other causes of crying, pain or distress have been excluded.

The Panel considers that the reduction of gastrointestinal discomfort is a beneficial physiological effect.

3. Scientific substantiation of the claimed effect

The applicant stated that a literature search was performed using the following key words: "beta-galactosidase" AND "infant" AND "crying", and that inclusion criteria comprised intervention studies in infants and young children in which lactase was administered and the effects on colic, flatulence, bloating or crying time were studied. No information was provided on the database which was used for the search, nor on the time limits of the search.

Through this literature search the applicant identified three human intervention studies (Kearney et al., 1998; Kanabar et al., 2001; Roy et al., 2004).

The study by Roy et al. (2004) investigated the effects of an infant formula fermented with *Streptococcus thermophilus* and *Bifidobacterium breve*, both of which can produce beta-galactosidase, and thickened with maize and potato starch, compared with an unfermented infant formula with no added starch. The Panel notes that this study does not allow the assessment of an independent effect of beta-galactosidase from *Streptococcus thermophilus* and considers that no conclusions can be drawn from this study for the scientific substantiation of the claim.

In the two other studies (Kearney et al., 1998; Kanabar et al., 2001), which were provided as supportive evidence by the applicant, beta-galactosidase other than beta-galactosidase from *Streptococcus thermophilus* was added to infant formulae before feeding. The Panel considers that no conclusions can be drawn from these studies in relation to a claim on beta-galactosidase from *Streptococcus thermophilus*.

The Panel notes that no human studies from which conclusions could be drawn for the scientific substantiation of the claim were provided by the applicant.

The Panel concludes that a cause and effect relationship has not been established between the consumption of beta-galactosidase which is produced by *Streptococcus thermophilus* (subsequently inactivated) during fermentation of an infant formula and reduction of gastrointestinal discomfort.

CONCLUSIONS

On the basis of the data presented, the Panel concludes that:

- The food constituent, beta-galactosidase from *Streptococcus thermophilus*, under the conditions of use proposed by the applicant, is sufficiently characterised.
- The claimed effect proposed by the applicant is "reduction of gastro-intestinal discomfort". The target population proposed by the applicant is infants and young children. Reduction of gastrointestinal discomfort is a beneficial physiological effect.
- A cause and effect relationship has not been established between the consumption of beta-galactosidase which is produced by *Streptococcus thermophilus* (subsequently inactivated) during fermentation of an infant formula and reduction of gastrointestinal discomfort.

DOCUMENTATION PROVIDED TO EFSA

Health claim application on beta-galactosidase from *Streptococcus thermophilus* and reduction of gastrointestinal discomfort pursuant to Article 14 of Regulation (EC) No 1924/2006 (Claim serial No: 0068_FR). January 2014. Submitted by Specialised Nutrition Europe (SNE).

REFERENCES

Hyman PE, Milla PJ, Benninga MA, Davidson GP, Fleisher DF and Taminiau J, 2006. Childhood functional gastrointestinal disorders: neonate/toddler. Gastroenterology, 130, 1519-1526.

Kanabar D, Randhawa M and Clayton P, 2001. Improvement of symptoms in infant colic following reduction of lactose load with lactase. Journal of Human Nutrition and Dietetics, 14, 359-363.

Kearney PJ, Malone AJ, Hayes T, Cole M and Hyland M, 1998. A trial of lactase in the management of infant colic. Journal of Human Nutrition and Dietetics, 11, 281-285.

Roy P, Aubert-Jacquin C, Avart C and Gontier C, 2004. Benefits of a thickened infant formula with lactase activity in the management of benign digestive disorders in newborns. Archives de Pédiatrie, 11, 1546-1554.

Shamir R, St James-Roberts I, Di Lorenzo C, Burns AJ, Thapar N, Indrio F, Riezzo G, Raimondi F, Di Mauro A, Francavilla R, Leuchter RH, Darque A, Hüppi PS, Heine RG, Bellaïche M, Levy M, Jung C, Alvarez M and Hovish K, 2013. Infant crying, colic, and gastrointestinal discomfort in early childhood: a review of the evidence and most plausible mechanisms. Journal of Pediatric Gastroenterology and Nutrition, 57 (Suppl. 1), S1-45.